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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,888	07/19/2001	David Lewis	206451US6PCT	8005

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EXAMINER	
MITCHELL, TEENA KAY	

ART UNIT	PAPER NUMBER
3761	14

DATE MAILED: 06/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,888	LEWIS ET AL.	
	Examiner	Art Unit	
	Teena K Mitchell	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Regarding the remarks on page 5 of applicants response to the office action, dated 03/13/03 (paper number 13) with respect to Table 3. The examiner is uncertain as to what applicants contemplated as the best mode for carrying out the invention at the time of filing the application and requests clarification. The examiners concern is 1) if the first two rows of data in TABLE 3 are not the best mode, are the other rows the better mode? 2) Applicant is willing to correct the data in the first two rows of TABLE 3 to make them the best mode. Thereby, making it unclear if the applicant actually had possession of the best mode at the time of filing and 3) If applicant now wants to amend the first two rows of data in TABLE 3, could this constitute new matter. Applicant is requested to address the examiner's concerns in response to this office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jager et.al. (5,676,930) in view of Ashurst et.al. (6,143,277).

Jager in a pressurized metered dose inhaler discloses a solution comprising an active ingredient, a hydrofluorocarbon propellant, and a cosolvent (Abstract, col. 2, lines 20-67).

The difference between Jager and claim 11 is the inhaler having an internal surface material selected from the group consisting of stainless steel and anodized aluminum.

Ashurst in an MDI teaches an inhaler internal surface material selected from the group consisting of stainless steel and anodized aluminum providing a well-known material for use with the internal surface of an inhaler which is not affected by the drug formulation (Col. 4, lines 27-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ any well-known material for the internal surface of the inhaler of Jager doing so would have provided a well-known material not affected by the drug formulation including the stainless steel and anodized aluminum taught by Ashurst.

With respect to claim 12, Jager discloses wherein said solution further comprises a low-volatility component (Col. 4, lines 56-67 and Col. 5, lines 1-10).

With respect to claim 13, Jager discloses wherein said low-volatility component is selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate (Col. 4, lines 56-67 and Col. 5, lines 1-10).

With respect to claim 14, Jager discloses wherein said active ingredient is selected from the group consisting of B2 agonists, steroids, anticholinergic agents, and mixtures thereof (col. 3, lines 36-67 and Col. 4, lines 1-28).

With respect to claim 15, Jager discloses wherein said active ingredient is ipratropium bromide, oxitropium bromide, and tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 16, Jager discloses wherein said co-solvent is ethanol (Col. 5, lines 1-10).

With respect to claim 17, Jager discloses wherein said propellant is HFA 227, HFA 134a and mixtures thereof (Col. 2, lines 52-67).

With respect to claim 18, Ashurst teaches wherein part or all of said internal surface is stainless steel (Col. 4, lines 27-46).

With respect to claim 19, Ashurst teaches wherein part or all of said internal surface is anodized aluminum (Col. 4, lines 27-46).

With respect to claim 20, Jager discloses wherein said solution comprises a low-volatility component selected from the group consisting of propylene glycol, glycerol, polyethylene glycol, and isopropyl myristate (Col. 4, lines 64-67 and Col. 5, lines 1-10); said active ingredient is selected from the group consisting of B-adrenergic agonists, ipratropium, oxitropium bromide, tiotropium bromide (Col. 4, lines 1-29), said co-solvent is ethanol (Col. 5, lines 5-10); said propellant is selected from the group consisting of HFA 227, HFA 134a, and mixtures thereof (Col. 2, lines 52-67); and Ashurst teaches part or all of said internal surface is stainless steel (Col. 4, lines 27-46).

With respect to claim 21, Jager discloses wherein said active ingredient is ipratropium bromide (Col. 4, lines 1-29).

With respect to claim 22, Jager discloses wherein said active ingredient is oxitropium bromide (Col. 4, lines 1-29).

With respect to claim 23, Jager discloses wherein said active ingredient is tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 31 see rejection of claim 20 above.

With respect to claim 32, Jager discloses wherein said active ingredient is ipratropium bromide (Col. 4, lines 1-29).

With respect to claim 33, Jager discloses wherein said active ingredient is oxitropium bromide (Col. 4, lines 1-29).

With respect to claim 34, Jager discloses wherein said active ingredient is tiotropium bromide (Col. 4, lines 1-29).

With respect to claim 42, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 43, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 44, Jager discloses wherein said active B-adrenergic agonist is formoterol (Col. 4, lines 23-28).

With respect to claim 24, while Jager does not disclose the specific ingredient flunisolide. He does disclose that anti-inflammatories can be used. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the active ingredient to be flunisolide as such is a well-known anti-inflammatory drug (Col. 4, lines 1-32).

With respect to claims 25, 26, 28-30, 35-37, 39-41 note rejection of claim 24 above.

With respect to claims 27 and 38, while Jager does not disclose the specific ingredient mometasone furoate. He does disclose that steroids can be used. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the active ingredient be mometasone furoate as such is a well-known corticosteroid (Col. 4, lines 1-32).

Response to Arguments

Applicant's arguments with respect to claims 11-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show MDI devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Teena Mitchell
Patent Examiner
Art Unit 3761
June 13, 2003